

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the amendments above and comments below.

Claims 1-45 are pending in the subject application. Claims 21, 22 and 26-46 have been withdrawn from consideration. The status of each of the pending claims is provided herein.

Accordingly, claims 1-20, and 23-25 are presented for examination on the merits

The amendment filed November 13, 2004 was considered non-compliant because three of the claim status identifiers were incorrect. The proper claim status identifiers have been provided and the claims are presented herein. No other changes to the amendment have been made. The following remarks were presented in the amendment filed November 13, 2003 and repeated hereinbelow for the Examiner's convenience.

The language of claim 1 has been amended merely to make explicit that which was implicit in the original claim. Claims 2 and 3 have been amended to delete reference to genes associated with a tumor; claims 10 and 11 have been amended to delete reference to specific genes. Claim 18 has been amended to further define a genetically tractable organism.

No new matter is added by the amendments to the claims.

A copy of the Supplemental Information Disclosure Statement and Form 1449 filed June 25, 2002 are enclosed herein, together with the stamped post card which indicates that a Form 1449 had been filed. Accordingly, Applicant respectfully requests that the reference cited on the Form 1449 be considered by the Examiner.

**I. Rejection of Claims 1-20 and 23-25 Under 35 U.S.C § 112, Second Paragraph**

Claims 1-20 and 23-25 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed as follows.

Claim 1 has been amended to more specifically define the secondary site mutation as one which results in a gene or protein that is non-functional. The claim has also been amended to clarify that the identity of the gene or protein effected by the secondary site mutation is determined in order to provide a secondary drug target. Thus, these amendments to claim 1 merely make explicit that which was implicit in the original claim language and do not substantively alter the claim.

Claims 2 and 3 have been amended to more particularly define the primary site mutation as one which is found in a human tumor cell.

Applicants acknowledge the finality of the restriction requirement and have elected p53 as the gene comprising a primary defect.

Claims 1-20 and 23-25 are rejected under 35 U.S.C § 112, second paragraph. The Examiner states that the claims are indefinite for failing to particularly point out and distinctly claim the subject which applicant regards as the invention.

It is respectfully submitted that the rejection of claim 1 is rendered moot by the amendment thereto.

It is respectfully submitted that the rejection of claim 2 is rendered moot by the amendment thereto.

The Examiner states that claims 3 and 12 are vague and indefinite in that the metes and bounds of the phrase "analogous or homologous to a defect found in . . ." because it is unclear what the degree of sequence identity or functional similarity is required.

This ground of rejection is respectfully traversed. The specification clearly defines the terms "analogous" and "homologous." At page 12 of the specification the terms "analogous" and "homologous" are defined as follows. "Two nucleic acid molecules are determined to be homologous if their nucleic acid sequences share a similarity of greater than 40% as determined by HASH-coding algorithms" The specification also states that homologous genes have a direct relationship among a family of genes in which certain sequences or domains are strongly conserved among the family members. The specification also provides an example of homologs: the yeast *mec1* gene and the mammalian genes encoding AT-related kinase. Thus, the specification provides the degree of sequence similarity and functional similarity

The term "analogous" is also defined at page 12 of the specification as referring to genes that are not related (do not have conserved sequences), but which have similar functions.

These definitions are also art recognized, as evidenced by the enclosed appropriate pages of Stedman's Medical Dictionary.

As such, the rejection of claim 3 and 12 under 35 U.S.C § 112, second paragraph is respectfully traversed.

The Examiner states that claims 10, 11, 14 and 24 are vague and indefinite because they specify that the secondary site is in a specified gene. This rejection is respectfully traversed.

Claims 10, 11, 14 and 24 specify that the secondary mutation is in a gene encoding a specified protein, but do not specify a particular gene encoding the protein. Thus, multi-allelic gene families, for example, are encompassed by this claim and specific alleles may serve as drug targets.

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It is respectfully submitted that cancellation of claim 14 renders this ground of rejection moot.

Accordingly, the rejection of claims 1-20 and 23-25 under 35 U.S.C § 112, second paragraph is respectfully traversed.